Staged Electronic Data Deliverable (SEDD)/ Automated Data Review (ADR) Project Implementation Overview

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DOCUMENT PURPOSE:

For the purpose of having a uniform delivery format for analytical data from laboratories performing environmental analyses, and to ensure that this data can be reviewed in a timely manner prior to use, certain United States Environmental Protection Agency (USEPA) and United States Army Corps of Engineers (USACE) contracts require implementation of the SEDD/ADR process. However, please note that any organization can implement the SEDD/ADR process to electronically transmit, review, and warehouse environmental analytical data from laboratories. This document outlines the personnel, information, software, and procedures required for the successful implementation of the SEDD/ADR process.

BENEFITS OF IMPLEMENTATION:

Studies have shown that using the SEDD/ADR process can save between 30 to 50% of analytical data review costs in time and money compared to similar manual data review processes. This implementation process allows data to be reviewed rapidly, making it ideal for Emergency Response (ER) and fast turnaround projects, thus providing the opportunity for adding a level of Quality Assurance (QA) in a timely manner.

Data is received from laboratories in the standardized SEDD format based on eXtensible Markup Language (XML). XML is an open, non-proprietary data exchange standard recommended by the World Wide Web Consortium (WC3). Since SEDD is agency and program neutral, the XML data files created by SEDD can easily be shared among various parties. The SEDD XML files are also ideal for long-term data storage since they are non-proprietary.

PLAYERS INVOLVED:

The following players are directly involved in the SEDD/ADR implementation process:

- Data Review Chemist (from Federal Agency or Federal Agency Contractor)
- Laboratory Personnel

PROJECT IMPLEMENTATION STEPS:

Once all necessary software has been correctly installed, the following implementation steps must be completed:

Step No.	*Step Title*
Step 1	Data Review Chemist Creates the ADR Project Library Based on the Quality Assurance Project Plan (QAPP)
Step 2	Laboratory Conducts Sample Analysis Based on the QAPP
Step 3	Laboratory Reports Sample and Quality Control (QC) Results in the SEDD eXtensible Markup Language (XML) Format
Step 4	Laboratory Checks the SEDD XML Files to Ensure the Files Conform to SEDD Specifications and Project Requirements. Laboratory Reviews both SEDD Checker Defect Report and ADR Non-Conformance Report and Ensures All Correctable Errors are Resolved Prior to Delivery
Step 5	Laboratory Delivers the SEDD XML Files and Laboratory-Generated Non-Conformance Report to the Data Review Chemist
Step 6	Data Review Chemist Checks SEDD XML Files and Laboratory-Generated Non-Conformance Report
Step 7	Data Review Chemist Reconciles Discrepancies and Resolves Issues Between the Non-Conformance Report Generated by the Laboratory and the Non-Conformance Report Generated by the Data Review Chemist
Step 8	Data Review Chemist Performs Data Review on the Files
Step 9	Data Review Chemist Approves and Exports the Reviewed Data
Step 10	Data Review Chemist Inputs the Reviewed Data into the End Database

SOFTWARE AND DOCUMENTATION USED:

The following software products, tools, and documentation are used during the SEDD implementation process (see Further Information below):

- SEDD Generator Tool, which may be used by laboratories as one of the options to create the SEDD XML files. See Step 3 below.
- SEDD Stage 2a Checker Tool. See Step 4 below.
- USACE ADR Software, Versions 6.2 or earlier, and 8.1 and above – Laboratory Version. See Step 4 below.
- USACE ADR Software –Versions 6.2 or earlier, and 8.1 and above – Consultant Version. See Step 6 below.
- End databases [e.g., USEPA's Scribe, USACE's Environmental Data Management System (EDMS)]
- USEPA-approved SEDD Document Type Definitions (DTDs) available for download from the USEPA SEDD Web site. Please note that only USEPA-approved DTDs can be used for the purpose of this implementation.
- SEDD Specifications, Version 5.0
- SEDD Valid Values
- SEDD Parser Tool (required only if using USACE ADR software Version 6.2 or earlier)

IMPLEMENTATION PROCESS OVERVIEW:

Step 1: Data Review Chemist Creates the ADR Project Library Based on the Quality Assurance Project Plan (QAPP)

The Data Review Chemist (working for the Federal Agency or Federal Agency Contractor) creates an ADR Project Library, which is then reviewed by the laboratory. (This ADR Project Library must be based on the requirements provided within the project's QAPP.) The review is conducted to ensure that all parties understand the QAPP requirements for sample analysis and analytical data review. The completed ADR Project Library is sent to the laboratory **prior** to arrival of project samples at the laboratory.

Note: It is recommended that this process be implemented by requesting the laboratory to provide compliant SEDD Stage 2a files. SEDD Stage 2a files allow for the review and validation by ADR of all analytical results reported by the laboratory based on holding times and method quality control (method blanks, Laboratory Control Samples, Matrix Spikes, and Matrix Spike Duplicates).

Step 2: Laboratory Conducts Sample Analysis Based on the QAPP

Step 3: Laboratory Reports Sample and Quality Control (QC) Results in the SEDD eXtensible Markup Language (XML) Format

The laboratory generates the SEDD XML files based on the USEPA-approved SEDD DTDs and the ADR Project Library. These SEDD XML files can be created using any of the following:

- Laboratory's internal Laboratory Information Management System (LIMS)
- SEDD Generator Tool (provided by USEPA)
- Third-party software vendors

Step 4: Laboratory Checks the SEDD XML Files to Ensure the Files Conform to SEDD Specifications and Project Requirements

The laboratory must ensure that the SEDD XML files conform to the USEPA-approved SEDD DTDs and contain the required SEDD valid values. This check can be performed by uploading the file to the SEDD Stage 2a Checker Tool. If the SEDD XML files conform to the USEPA-approved SEDD DTDs, the laboratory imports these files into ADR Version 8.1 or above (Laboratory Release). The SEDD files are reviewed against the ADR Project Library in the Contract Compliance Screen (CCS) module of the ADR software. ADR generates a Non-Conformance Report identifying items that do not conform to the ADR Project Library requirements, e.g., missing QC data, invalid dates, or incorrect numbers. The laboratory reviews this report and makes any necessary corrections to the SEDD XML file. This review process continues until all non-conformances within the laboratory's control are corrected. The laboratory addresses any

non-conformance that is not within the laboratory's control [e.g., insufficient sample for a Matrix Spike/Matrix Spike Duplicate (MS/MSD)] via a brief explanation in the Non-Conformance Log. The laboratory then generates a final Non-Conformance Report (in hard copy or .pdf format), which must be forwarded with the final SEDD XML file.

Note 1: The SEDD Parser Tool parses and converts a SEDD file into a set of files (ADR files) that can be imported into ADR Version 6.2 or earlier (Laboratory Release). The SEDD Parser Tool is not required for ADR Version 8.1 or above since the software was enhanced to allow direct import of SEDD files.

Note 2: After a laboratory gains experience and starts generating compliant SEDD files, the SEDD Stage 2a Checker Tool need not be used to perform the file checking and correction process.

Step 5: Laboratory Delivers the SEDD XML Files and Laboratory-Generated Non-Conformance Report to the Data Review Chemist

The laboratory transmits the final SEDD XML files and the final Non-Conformance Report (in hardcopy or .pdf format) to the Federal Agency and/or Federal Agency Contractor Data Review Chemist.

Step 6: Data Review Chemist Checks SEDD XML Files and Laboratory-Generated Non-Conformance Report

The Data Review Chemist must be from the Federal Agency and/or Federal Agency Contractor. The Data Review Chemist imports the SEDD XML files either directly into ADR (ADR Version 8.1 and above, Consultant Release) or by converting the XML files into ADR import files using the SEDD Parser Tool (ADR Version 6.2 and earlier, Consultant Release). Once imported into ADR, the files are reviewed against the same ADR Project Library used by the laboratory in the CCS module. A second Non-Conformance Report is generated, which should be identical to the one received from the laboratory.

Step 7: Data Review Chemist Reconciles Discrepancies and Resolves Issues Between the Laboratory-Generated and Data Review Chemist-Generated Non-Conformance Reports

a. Reconciliation of Discrepancies: If the Non-Conformance Reports are not identical, the Data Review Chemist must contact the laboratory and resolve all non-conformances. This may occur if the SEDD data files are corrupted during transmission or if the laboratory and Data Review Chemist use different ADR Project Libraries.

b. Resolution of Issues: If the Non-Conformance Reports are identical, the Data Review Chemist may still contact the laboratory if the Data Review Chemist feels there are significant non-conformances that have not been addressed by the laboratory.

Step 8: Data Review Chemist Performs Data Review on the Files

Once all non-conformances have been reconciled and resolved, the Data Review Chemist proceeds with the review of the ADR files in the ADR Data Review module. The ADR Data Review module applies validation qualifiers to the data based on the ADR Project Library data review requirements. The Data Review Chemist then reviews the qualified data and manually edits the validation qualifier based on his or her professional judgment. The Data Review Chemist must document the reason for all manually edited validation qualifiers. The Data Review Chemist may also refer to the hardcopy data packages for issue resolution.

Step 9:Data Review Chemist Approves and Exports the Reviewed Data.

Upon completing the automated review and professional review of the data, the Data Review Chemist acknowledges completion of their data review using the ADR software and exports the reviewed files for input into the appropriate end database.

If the Federal Agency and/or Federal Agency Contractor policy requires approval by another individual, the approving individual imports the reviewed files, acknowledges his or her approval within the ADR software, and exports the reviewed and approved files for input into the appropriate end database.

Step 10: Data Review Chemist Inputs the Reviewed Data into the End Database

The reviewed and approved (if applicable) data is uploaded into the end database [e.g., EDMS for USACE projects and Scribe for USEPA Emergency Response (ER) projects].

FURTHER INFORMATION:

Please contact Anand R. Mudambi at mudambi.anand@epa.gov or 202-564-2817 if you have any questions regarding SEDD/ADR project implementation or to obtain any of the following software products/tools:

- ADR
- EDMS
- Scribe
  - USEPA ERT Website (for obtaining information on and downloading Scribe): http://www.ertsupport.org/scribe_home.htm
- SEDD Parser Tool
- SEDD Generator Tool: http://sedd.fedcsc.com/
- SEDD website: http://www.epa.gov/superfund/programs/clp/sedd.htm
  - SEDD Document Type Definition (DTD) document: http://www.epa.gov/superfund/programs/clp/seddspec5.htm
- SEDD Stage 2A Checker Tool website: http://epasmoweb.fedcsc.com/seddchecker/uploadservlet